TITLE: Modeling Phase III microbicide clinical trial costs

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Issues: Trial sizes for Phase III microbicide studies have been estimated between 4,000 and 10,000 participants and are expected to take between 2-5 years to complete. Sample sizes are based on statistical requirements, incidence of HIV transmission and drop-out rates resulting in difficult financial and logistical planning. Furthermore, an exhaustive search for existing planning tools proved futile making it necessary to develop a trial specific modeling tool.

Description: Initially, a static planning model was developed that comprehensively estimated costs and timeline based on one sample size. Inputs such as drug product costs, data management, and site costs were derived from proposals from organizations bidding on the work. A dynamic model was then built that allows user input to vary study size, enrolment forecasts, number of sites, site roll out, costs associated with salaries and laboratory procedures with a resultant output of overall study timeline, timeline of visits, and cash flow.

Lessons Learned: The static model was a cumbersome way to study scenarios and did not allow for understanding of the cost drivers. The dynamic model allows for analysis of the impact of changes in input parameters on the major cost centers. Not surprisingly, the major determinate of trial costs is the trial size and time. The relative contributions of secondary drivers become evident and thus actionable in a dynamic model. This model confirms that the cost of conducting licensure quality clinical research in developing countries is of the same magnitude as in the developed world.

Recommendations: Planning for large scale studies should involve iterative analysis of scenarios so that the most cost effective trial achieving the desired endpoint(s) can be designed and the full implications of financial commitments can be understood prior to implementation.